

FOOD SAFETY AND INSPECTION SERVICE

SALMONELLA ENTERITIDIS IN SHELL EGGS AND
SALMONELLA SPP. IN LIQUID EGG PRODUCTS
RISK ASSESSMENTS TECHNICAL MEETING

Friday, October 22, 2004

9:10 a.m.

Hyatt Regency Capital Hill

PARTICIPANTS:

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Dr. Carl Schroeder
Dr. Wayne Schlosser
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C O N T E N T S

	PAGE
Opening Remarks/Moderator - Mr. Loren Lange	4
Welcome - Dr. Barbara J. Masters	4
Overview - Mr. Loren Lange	7
Current Risk Management Policy Questions about Salmonella in Eggs - Ms. Victoria Levine	13
The FSIS Risk Assessment, Part I - Dr. Carl Schroeder	21
The FSIS Risk Assessment, Part II - Dr. Wayne Schlosser	40
Questions and Answers	59
Closing Remarks - Mr. Philip Derfler	87

P R O C E E D I N G S

MR. LANGE: Good morning again. This is, I guess, the official "good morning."

My name is Loren Lange. I'm the Deputy Assistant Administrator for the Office of Public Health Science at FSIS, and I will be your moderator for today's meeting.

I would first like to introduce Dr. Barbara Masters, who is our Acting Administrator at FSIS, and she would like to make a few opening remarks.

DR. MASTERS: And I appreciate your indulgence. I'm going to stay seating. I'm not completely two-legged this morning. I'm three-legged. I brought my crutch with me, so please bear my indulgence as I sit this morning.

But I do appreciate everyone's attendance this morning, and on behalf of the Food Safety and Inspection

Service, I want to welcome all of you to the public meeting to discuss Salmonella risk assessments.

At FSIS we recognize the important role the public involvement has in all segments in rule making and policy development. It's good to see so many of you in attendance today to discuss the risk assessments on the quantitative analysis of Salmonella Enteritidis in shell eggs and of Salmonella in pasteurized liquid egg products.

This is an extremely important process, one that provides regulatory agencies such as our own with a solid foundation for policy changes that can improve public health.

And in an effort to expand our reach for this public meeting, this meeting is actually being webcast. More than 14 sites have signed up to participate in this meeting using this format, and it's a first time we've actually used this format for a public meeting to enhance our ability to include public participation in a public meeting such as this.

By utilizing this form of technology, we're able to connect with a much broader audience, and in turn will be able to get much more inclusive discussions. So Loren, Mr. Lange, our moderator, will actually be able to receive questions through the computer, and those that are joining us by webcast will not only be able to see the discussion, but will actually be able to participate and ask questions of the panel through this process.

Risk assessments certainly provide critical information that allow risk managers to better identify interventions that can lead to public health improvements. These interventions can be regulatory actions when necessary, but they can also be non-regulatory actions, such as educational initiatives or even research to close critical data gaps.

The draft, "Salmonella Risk Assessments" will help us to identify those data gaps and target research that should have the greatest value in terms of public health. We have already begun the process to identify research needs based on public health. Risk assessments will allow us to continue this work in a structured manner.

I think you're aware that our agency has already completed several risk assessments, including those for the Salmonella Enteritidis in eggs, E-Coli 0157H7 in ground beef, and Listeria Monocitogenes in ready-to-eat meat and poultry products. The results of these risk assessments have been used to develop food safety risk management strategies to further protect the public from food-borne illnesses.

These risk assessments are good examples of how we must continually update our assessments based on new information. Data from these risk assessments provide the scientific basis for decision making. I truly am encouraged by the dedication that brought all of you out here today, and

I look forward to a productive forum.

During this meeting, you're going to hear from several of my FSIS colleagues, and I encourage all of you to think critically and to offer comments about the path that we are taking. Your work will go a long way in helping our agency develop and implement policies that will improve public health. We firmly believe that our continued success is dependent on meticulous examination of current food safety hazards, and the systematic use of our resources in addressing those hazards. I am confident that this meeting is a step in the right direction.

I certainly appreciate all of you coming. I look forward to the discussion and the recommendations. Now, let's get to work. Again, thanks to all of you for coming.

Mr. Lange?

MR. LANGE: Thank you, Dr. Masters.

The next item on the agenda is referred to as an overview. So I am presenting an overview. I'd like to cover really, just three topics here. I want to make some general comments about quantitative risk assessments sort of for the benefit of others like myself that aren't currently, you know, heavily involved in the topic. Then I will go over our agenda for today and review the agenda. And finally, I will discuss about how we will handle comments during the question and answer period.

Today we will be presenting information on two quantitative risk assessments, and I emphasize the word "quantitative" because this is one particular type of risk assessment. The quantitative risk assessment, for us at least, involves the development and execution of a model that's designed to simulate some portion or all of the, sort of the production, processing, handling, preparation, and consumption of food products.

These are microbial risk assessment models. They typically begin with an input, which is data on some level about a hazard, a pathogen, and they usually end with an estimate of some estimate of food borne illness resulting from consumption. And in between, we're talking about there's a lot of equations and relationships and data files that sort of estimate, you know, what happens along that process of producing, handling, and consuming food.

Today you will hear probably several references to risk management questions. They are important. They're very important to us. I guess one could think of them as the sort of minimum building codes for risk assessment.

You know, if the risk managers need to evaluate a certain parameter, or a certain mitigation strategy, or a certain intervention, or even education program, the model has to be developed so that it allows for consideration of that variable or that strategy.

Risk assessors never want to hear, after spending a lot of time and money that, "Hey, great model, but it's not of much use to us." That's why we pay very close attention to the risk management questions, and you'll hear, you know, a lot about them today.

You will hear speakers talk about the baseline assessment. Baseline assessment in a quantitative risk assessment is really the best estimate of where we are today.

It's the initial model without any modifications, and it is, you know, designed to sort of give us -- reflect the best estimate of current reality.

You also will hear the term "anchoring." This has nothing to do with deep sixing the model or putting it at the bottom of the ocean. A model is anchored when it's sort of is designed or adjusted to sort of accommodate where we do have real hard data. If we have hard data, you know, that everybody agrees to on food borne illness, we would sort of anchor a model so that the output sort of does reflect what we know about reality.

In an ideal world, a model could be anchored at several points along from the inputs to the outputs, but we know that's not a reality. So -- but when we do have hard data, we do like to keep our model best anchored in reality.

When you think of anchoring, and sort of the uncertainty of data, it's sort of a lead-in to a point I want

to make about quantitative risk assessment. We think that it's probably best that people sort of think about the relative answers that a quantitative risk assessment provides.

It's certainly our belief that if you had two models, one of which predicted a reduction in illness from 400,000 illnesses down to 200, another predicted, you know, from 200,000 illnesses down to 100, we would consider those the same model, and it's a way of us wanting to make a point that you really should look at the change, and if they -- you know, if they both -- if people agree that the assumptions are reasonable, and the model is a reasonable reflection of reality, you know, it's the relative change we're focusing on, and not the absolute number of illnesses.

Finally, I'd like to say that certainly, personally I'm convinced that there's probably no better way to sort of identify data gaps and research needs than actually participate in trying to develop a model that simulates reality.

It's a long time ago, but in the '60s when I started in the federal government, I was trying to build a different type of model, but I still remember from that. I mean, that's -- the first thing you learn is, "Gosh, I wish we had this data. We really need this." So the process of trying to develop a model is probably the best way we have of

really identifying the data gaps and what we need.

Next I'm just going to quickly refer to the agenda, the second point I wanted to cover. After this overview, Ms. Victoria Levine will, from the Office of Policy, will talk about the risk management questions. Then Dr. Carl Schroeder will give us a background on the microbiology of Salmonella in eggs, and the epidemiology of Human Salmonellosis. Then we'll take a break.

And after the break, Dr. Wayne Schlosser will actually review the two models that we're talking about. He's provide a description of these models and their results.

And then finally -- no, not finally, we'll have a question and answer period. Sorry Phil. And Mr. Phil Derfler from the Office of Policy will provide our closing remarks. That will be the end of the day.

I'd now like to explain just a little bit about how we're going to handle this question and answer period. We're going to first open it up to questions from the audience here. And then we will deal with those first. And next, with a little technical assistance, I will learn how to read the questions and identify who's sending questions in via the webcasting on this computer. I'm going to need a little help at the break, I think. I wasn't quite sure that I could do it yet.

And finally, we may have people that find out that

they're at a site and can't get a question typed in. We also have provided for phone-ins, so there will be a third type of question that we can deal with, phone calls at the end.

In generally, we've sort of discussed among ourselves, we'd like questions to sort of be of a, you know, a nature of clarification, and helping one sort of generally understand what was done as opposed to getting in questions that lead to a lengthy debate or discussion of, you know, how a model could've been done or should've been done. I'm not sure exactly what a question of clarification is versus discussion, but we'll know it when we hear it probably. So I assume that's how we'll make those decisions.

And then closing; before I introduced our first presenter, we're presenting two draft risk assessments today.

I want to re-emphasize the word "draft." These are drafts.

FSIS wants your feedback on these drafts, and if you have data or aware of data that could help us improve these two draft risk assessments, please let us know about it.

As you may be aware, detailed descriptions, lengthy documents describing these risk assessments were posted October 18th on the FSIS website. The Federal Register announcing this meeting provided for that said we would take comments up to 30 days. So we're sort of now, we were a couple of days late on getting the risk assessments posted. So 30 days from October 18th we're certainly willing to

accept comments.

With that I'd like to introduce our first speaker for the day, Ms. Victoria Levine. Victoria has worked in the Office of Policy and Program Development at FSIS for the past 11 years. She is a graduate of Rutgers University, School of Law in Camden.

Ms. Levine?

MS. LEVINE: Thank you, Loren. I'm Victoria Levine, and I am standing up.

Now that we have that out of the way -- okay.

(Asides.)

MR. LANGE: Pull the mic down a little bit and towards you. I do not have --

MS. LEVINE: You do not. Okay. Well, then I guess all attention's on me. Technical glitch. Yeah. Okay.

Well, I'm going to talk a little bit about risk assessment just to lay a general foundation, and then I'm going to talk a little bit about risk management. Nothing too difficult. I'll let them take care of the difficult.

Here is my first slide. Isn't that pretty? So what is risk assessment? Risk assessment is an estimation of the likelihood of adverse effects that may result from exposure to a specified health hazard, or from the absence of a beneficial influence.

FSIS's Salmonella risk assessments are

comprehensive, quantitative models. You'll hear that over and over again. And they characterize public health affects associated with the consumption of Salmonella Enteritidis contaminated shell eggs and Salmonella species adulterated egg products.

So now that we know what risk assessment is, what is a risk management question? It is a question; it is asked by -- I have managers, but really it's asked by people who foresee developing policies that would benefit from risk assessment support. FSIS risk managers are interested in developing policies that will reduce the risk of human illness from SE in shell eggs and Salmonella species in egg products.

You may say, "Well, why is FSIS interested in that?" That may be fairly obvious to some of us, but maybe not to all. Humans can contract Salmonella from eating contaminated shell eggs and egg products. Okay. Yeah, that's pretty obvious. However, between 1976 and 1995, there was an eight fold increase in reported Salmonella Enteritidis infections to the CDC, and of that eight fold increase, 75 percent of those cases were associated with foods containing undercooked eggs. So you might say that undercooked eggs were the smoking gun.

I'd like to think that maybe the smoking gun has sort of shifted to raw vegetables these days, but we're not

interested in raw vegetables. So we got to stick with what we're interested in.

So now we know what risk assessment is. We have some idea of what a risk management question is. So let's specifically look at the two FSIS risk assessments. What is the purpose of these risk assessments? Well, the purpose is to assist FSIS in evaluating our risk management options for developing shell egg and egg products' performance standards, or some other mechanism that is intended to significantly reduce the risk, again, of illnesses from SE in shell eggs and Salmonella species in egg products.

All right. So we have two risk assessments. Some people may wonder, "Why do you have two?" We have two because they focus on different pathogens. Okay.

Most cases of food-borne Salmonellosis in the U.S. are associated with shell egg consumption. Okay. The predominant Salmonella serotype in shell eggs is Salmonella Enteritidis. SE is usually transmitted during the formation of the egg within the chicken. It is trans-ovarian, means when it comes out of the chicken, it is in the egg.

Contaminated egg products, however, often include a variety of Salmonella serotypes in addition to SE. So you might have SE in an egg product, but you're -- you may also have, if you have it, typhimurium, hydelburg (phon.), montevedao (phon.). Okay. And this partly comes about

because you may have contamination on the shell of the egg. It may be on the equipment used to process the egg, or it may be another environmental source in the breaker plant, you know, in the transfer room, blah, blah, blah, whatever. Or it may actually come in on the egg from the laying house. So you have to worry about other things.

Okay. So now that we know all of that, we're actually going to get to the risk management questions. The risk managers at FSIS posed three risk management questions to the risk assessors. They said, "This is what we need to know about SE in shell eggs." The first risk management question was: What is the number of illnesses per serving, and what is the annual number of illnesses from Salmonella Enteritidis cells in pasteurized and non-pasteurized shell eggs?

The second risk management question was; just listen to this: What is the effect of the temperature and length of time in days before eggs are collected after they are laid by the hen, and then refrigerated and further processed on the estimated risk of illness? That is not the most artfully written question.

What we really want to know is, an egg is laid; it is not collected immediately. There is some length of time, could be just a couple of hours. It could be 24; it depends. And meanwhile -- so it's lying out in the environment. The

temperature is whatever.

Once the egg is collected, there are various things that could be happening to it. Some places, at some farms they're going to stick it into a refrigerator. That refrigerator may be at 60 degrees. It may be at 45 degrees, or they may not stick it in a refrigerator.

And again, as it moves through the system, it's eventually going to get to a point where it's processed. I mean, something happens to it. It's washed. It is refrigerated; you know, something.

We want to know, what does the effect -- what does all of this -- how does this affect the egg? If there's SE in the egg, depending on all these variables, is there going to be growth? And -- or if, in fact, they -- let's say they do get it into a refrigerator pretty quickly. If there is SE in the egg, how much is it going to slow it down? That's what that question is aiming at, and I promise, we'll write it better next time.

And the final risk management question that had to do with SE is; what is the number of Salmonella Enteritidis cells in shell eggs before and after a specified pasteurization scenario?

We then posed two questions -- two risk management questions addressing a Salmonella species in egg products. The first one is: What is the number of illnesses per

serving, and the annual number of illnesses from Salmonella species cells in pasteurized egg products; for example, liquid whole eggs, yolks, egg whites and various other iterations?

The second was: What is the number of Salmonella species cells in a liter of egg products, again, whole, yolk, albumen, before and after a specified pasteurization scenario?

And that's what Carl is going to -- well, no. yeah, I guess he is. One of those guys is going to tell us the answers.

Now, this is where you really, unfortunately needed the screen because this is where you can get the risk assessments if you haven't already. This is impossible to read with me holding it up, but here's what I'm going to tell you. If you go to our website, to our home page, www.fsis.usda.gov, let's see, right on the home page there was a direct link for this meeting and for the risk assessments. That's one way to find it.

If you went to the news and events link, you could also find it that way. If you go to, let's see, regulations, there's also a link on the left side of the web page for regulations and policies, and if you go there, and you look for FSIS notices, and then search for federal regulation notices, and you look for 2004, you will find federal -- I'm

sorry, federal register notices, you will find it there. So even if you can't read this, it's not all that hard to find.

So I wish you luck.

Thank you very much.

(Applause.)

MR. LANGE: Thank you, Victoria.

MS. LEVINE: You're welcome.

MR. LANGE: While she was talking, I was sort of remembering that one of my chores growing up in Iowa was to go out to the hen house and collect the eggs. And I always remember, well, if I didn't do it every day, I never had to worry about it because I knew those hens would sit on them and keep them nice and warm.

Our next speaker is Dr. Carl Schroeder, who will give us a background on the microbiology of Salmonella in eggs, and epidemiology of human Salmonellosis.

Dr. Schroeder currently serves as a risk analyst in FSIS Office of Public Health and Science. Prior to joining FSIS, he served as faculty research associate at the University of Maryland in College Park, Maryland. His research focused on a wide range of topics, including development of rapid methods for detecting bacterial pathogens in foods and bacterial antimicrobial resistance. Dr. Schroeder received a Ph.D. with a major in microbiology from Marquette University.

Dr. Schroeder?

DR. SCHROEDER: First, can everybody hear me okay with the microphone like this?

Okay. Good morning. It's my pleasure to be here today. I'd like to thank you all for coming to hear what we have to say, and also thank you to those who are joining by the webcast.

The bulk of my presentation will focus on providing a brief overview of the microbiology of Salmonella in shell eggs, and also the human -- the epidemiology of Human Salmonellosis. I'll do this primarily to provide background and context for the results of our risk assessment, which my colleague, Wayne Schlosser, will present after the break.

Do I just click on the left mouse button? I might need your help. It doesn't seem to be working.

(Pause.)

DR. SCHROEDER: Okay. Please indulge me for a few minutes before I begin the bulk of my talk to acknowledge several people. First I'd like to make mention of the principal architects of the risk assessment that are shown on this slide. Peg Coleman played a vital role throughout developing the risk assessments, and lent her expertise in issues regarding dose response throughout the assessments.

Eric Ebel was instrumental in developing the risk assessment models.

Neal Golden played a key role in describing the growth of Salmonella Enteritidis in shell eggs, in particular, the immunological aspects thereof.

Allan Hogue was the architect of our hazard characterization, which is described in chapter four of the risk assessment.

Abdel Kadry helped to mine several databases, in particular, the continuing survey of food intake by individuals.

Janell Kause was involved at the inception of the risk assessments, helped to formulate the risk management questions, and has played a key role in communicating between the risk assessors and the risk managers.

Heejeong Latimer lent her expertise for various modeling issues throughout the assessments.

Harry Marks was instrumental in developing the growth model and gave us statistical expertise.

Nate Quiring helped us to revise the document in light of reviewer comments.

Wayne Schlosser is the primary modeler for the risk assessments.

And I assisted by analyzing data for the risk assessments.

Next slide, please.

Five individuals shown here served as external peer

reviewers for our risk assessments. Doctors Scott Ferson and Maarten Nauta are risk assessment modelers and provided us with insightful comments on the structure of our model.

Professor Tom Humphrey is an expert in Salmonella Enteritidis in shell eggs. We cited a lot of Dr. Humphrey's work throughout our risk assessment, and we were happy to have him serve as a reviewer.

Christine Little and John Maurer both have expertise in aspects of Salmonella and epidemiology and food microbiology, and also provided helpful comments.

On the next slide please, I won't go through by name, but suffice it to say that several of our colleagues in the Risk Assessment Division helped by giving us informal comments throughout conducting and revising these risk assessments, and also their support throughout the process. And so that is greatly appreciated.

On the next slide, I just show this to show that a risk assessment of this size and complexity takes input and advice from many people. Our work benefitted greatly from interaction with these folks.

And lastly on the next slide, I'd like to thank our colleagues at the FDA, Center for Food Safety and Applied Nutrition, and at the Centers for Disease Control and Preventions. Those that CFSAN provided us with extensive and thorough comments which helped us greatly as we work to

generate the draft report you have in front of you.

A very important caveat, we did not, at this point, make all the changes suggested by CFSAN. We're still in the process of trying to do that, specifically for changes to the model, which are labor and time intensive.

Our colleagues at the Centers for Disease Control and Prevention are planning to review this draft risk assessment. They have not reviewed it at this point. We look forward to working with our colleagues from both CFSAN and CDC, as well as the public as we go forward in the next months to move towards a draft -- excuse me, move towards a final report.

Okay. On the next slide, please. I'll cover four main topics in my talk today. I'll give a brief background, again, to help place the risk assessment in context. We'll review the microbiology of Salmonella, paying particular attention to the growth of Salmonella Enteritidis in shell eggs.

We'll review the epidemiology of Human Salmonellosis, and during this time I'll rely primarily on publicly available data from our colleagues at the CDC. And lastly I'll offer two or three broad conclusions about where we stand, and that should set us up nicely for Wayne's presentation after the break.

Okay. Next slide, please.

And this is one -- don't do anything yet, but it's -- we'll have to click through because some things come flying in. So I'll cue you on that.

In 1996 FSIS, in collaboration with FDA, initiated a risk assessment to characterize the public health affects associated with consumption of *S. Enteritidis* contaminated eggs. That final report was published in 1998. The results of that assessment indicated that multiple interventions along the farm-to-table chain were necessary to reduce significantly the risk of illness from *S. Enteritidis* in eggs.

The results were useful inasmuch as they went towards developing programs such as the Egg Safety Action Plan. However, the results were not deemed sufficient for evaluating risk management options for developing performance standards in eggs.

On the next slide, please.

Since then, additional data have become available that we feel allows us to create improved risk assessments for *Salmonella Enteritidis* in eggs and *Salmonella* species in egg products. First, FSIS has conducted a national baseline survey to measure *Salmonella* levels in liquid egg products produced in the U.S. I do not have the reference here. It is in the report that's on the web. My colleague, Victor Cook, presented a summary of these results at this year's

International Association for Food Protection Meeting, and so they will also be in that abstract book.

Several experimental studies have clarified scientific issues associated with SE contamination in egg yolk, many of those by Professor Humphrey, who I referred to earlier.

Next.

The United Egg Board has sponsored an important study on the lethality kinetics of Salmonella species in liquid egg products. The results of that study allowed us to model pasteurization for liquid egg products, as we'll talk about in the next presentation.

And lastly another important development was that of a dose response model for Salmonella species that was developed by the Joint Experts on Microbial Risk Assessment under the purview of FAO/WHO. This dose response has been extensively reviewed, and for the most part, I believe, has international acceptance. We thought that it would be a dose response that was easy to defend, and one that reflects reality fairly well. Hence it's inclusion in our risk assessment.

Okay. Next slide, please.

So let's now take a brief look at the microbiology of Salmonella. I put this up here because one of the questions we sometimes get is, you know, "Hey, did you guys

forget to italicize "Enteritidis" in your report and so forth?" So *Salmonella Enteritidis*, if we look at the salmonellae, depending on the taxonomical scheme that you use, this is the one that's adopted by the CDC and the one that I prefer.

Salmonella species can be divided into two species; enterica and bongori you see in the left-hand column. Those species are further subdivided into sub-species. Enterica is further divided into sub-species. I won't go through all of them, but you see the six listed there.

Within each species there are multiple serovars, as you'll see there, different strains. There's a total of just under 2,500 serovars of *Salmonella*. So if we want to say it out, and we'll talk about Enteritidis, I would say, *Salmonella enterica*, subspecies, enterica serovar enteritidis. That's obviously long winded, and we don't want to say that or write that all the time, so we just say "*Salmonella Enteritidis*." When we refer to *Salmonella* species, generically that refers to any of the *Salmonella* species, including enterica serovar enteritidis.

Okay. Next slide, please.

Very briefly the *Salmonellae* are gram-negative, rod-shaped bacteria. They grow facultatively anaerobically, and they are motile by means of flagella.

The next slide, please.

They're members of the entero-bacteriaceae (phon.), that Salmonella. They're optimum growth temperature is around 37 degrees C, and they grow best at near neutral pH.

Next slide, please.

This is a very important point. Salmonella Enteritidis is transmitted to eggs through two routes. The first one, which we call trans-ovarian or vertical transmissions, describes the route whereby SE is introduced into the egg from infected ovaries or oviduct tissue before the egg is laid. That's the primary route of contamination for S. Enteritidis in shell eggs.

On the next -- yeah, thank you.

The next route is trans-shell or horizontal transmission, can result from fecal contamination of the eggshell. Today this is not a problem. There are stringent programs in place for washing eggs and so forth, and we don't see that a lot.

On the next slide, please.

Okay. I'll now provide, again, a brief background on the epidemiology of Human Salmonellosis and where we stand today. This -- the numbers given here are based on the seminal work of Paul Mead and his colleagues at the Centers for Disease Control and Prevention. You can see the reference down there at the bottom of the slide, but what they've estimated is that food-borne Salmonellosis in the

U.S. causes approximately 1.3 million illnesses, 15,600 hospitalizations, and 550 deaths each year.

A slight point of clarification I would like to make. The statement that 80 percent of food-born Salmonellosis comes from eggs, it is not correct. Eighty percent of Salmonella Enteritidis infections in humans appear to come from eggs, and that's with the caveat that that 80 percent is based on outbreak data, not taking into account sporadic cases.

On the next slide, please.

This is just one estimate of case costs per Salmonellosis. A case that does not require a physician visit is estimated to cost roughly \$440 due to lost productivity and so forth; a case requiring a physician visit is estimated just under \$1,000; a case which requires hospitalization, just under \$11,000; and one that results in death close to half a million. You do that math, keeping in mind the earlier estimates I gave you, it's reasonable to suspect that the annual, economic burden in food-borne Salmonellosis is approaching the \$2 billion mark.

I would encourage you to visit -- I apologize. That's a little bit tiny there, but the website at the bottom, if you go to the Economic Research Service of USDA, their home page, you'll be able to find links to their food-borne illness economic cost calculator, or something to that

effect, where they will explain their estimates and allow you to plug in different numbers, and it's a very good tool.

On the next slide, please.

Disease characteristics; symptoms for Salmonellosis include diarrhea, fever, abdominal pain or cramps, vomiting, headache, and nausea. The incubation period ranges from 8 to 72 hours with symptoms typically lasting up to one week, and the severity of infections varies. Most infections are self-limiting and do not require treatment with antibiotics. They resolve.

Some infections, however, can be quite severe, and we know, as I'll show you shortly, that in patients with underdeveloped or compromised immune systems, they can be fatal.

On the next slide, please.

About two to three percent of persons who experience Salmonellosis will go on to develop reactive arthritis, typically showing up 7 to 30 days after the onset of intestinal illness. Some others will go on to experience some of the sequelae you see here; urethritis, conjunctivitis, weight loss, oral ulcers and pneumonia.

And the next slide, please.

The question of how many cells of Salmonella does it take to cause illness in humans is to a degree, an open one. This is the dose response and outbreak data, a summary

that I've taken from the FAO/WHO report that I eluded to earlier, and the point that this slide is making is that at a dose of approximately 5-log_{10} for Salmonella. This is based on Salmonella Enteritidis Typhimurium and one or two others.

It varies, but somewhere between 50 and 75 percent of people ingesting that dose can be expected to develop symptoms of Salmonellosis.

The other important point to make from this slide is that the log dose that we've seen in past outbreaks has varied considerably. On the slide here, the black boxes indicate past outbreaks with the log doses there. The curve that you'll see is simply the median value and the center lines surrounded by the uncertainty associated with that log dose. But you can see that in some cases, as few as a 100 to 1,000 cells have been thought to cause illness, whereas in the upper right-hand of the graph, you'll see that at times ten to the tenth, ten to the ninth cells of Salmonella have been implicated in outbreaks.

Next slide, please.

Like many food-borne pathogens, when we look at the cases of Salmonellosis, we see a peaking in the summer and early fall months. Similar patterns have been documented for both outbreaks of Salmonellosis and for Salmonella positive spent hens at slaughter.

Warm temperatures allow for rapid growth of the

Salmonella. That's likely part of what underlies this graph.

We should also be aware that picnics and potluck suppers and these sorts of things, where outbreaks are commonly detected, typically take place in the summer months, and that also likely explains some of what you see here.

On the next slide, the incidents of Salmonella infections is, for the most part, a bimodal distribution. Again, this is common amongst food-borne pathogens. You'll see on the left-hand side of the graph that those at greatest risk for developing Salmonellosis are infants and young children. In normal, healthy adults, the risk of Salmonellosis is somewhat lower, and then as one becomes a senior citizen, you see more Salmonellosis.

The next slide, please.

This is a summary of data from the Centers for Disease Control and Prevention. It comes from their Salmonella annual summaries, and on the web, I believe, they have their summaries from 1976 up through 2002. It's a very useful resource, but what you can see here, and this is what Vicky eluded to earlier, beginning in the mid to late '70s, the top lines of the chart, we begin to see a steady increase in the number of Salmonella clinical isolates that peaked in the mid to late '80s and has tapered off thereafter.

I also show typhimurium for the sake of comparison, and you can see the trend that it follows, staying relatively

steady, and the lowest line on the chart, the one with the boxes is for Salmonella Enteritidis, and again, you see that it sort of mirrors the overall Salmonella data, in that it increases steadily throughout the '80s, reaching a high point in the mid- to early '90s, and then tapering off thereafter.

This data -- well, excuse me. This chart shows data through the year 2000. In the year 2002, there were just over 5,000 clinical isolates of S. Enteritidis reported to the CDC. So you can see that slight downward trend continues. We should all be happy by that. It's certainly partly the result of voluntary quality assurance programs, trace-backs, et cetera, that all of us, the industry in particular, have worked hard to implement.

On the next slide, please.

Period 1976 to 1995 saw an eight fold increase in infections with S. Enteritidis greater than 75 percent were associated with foods containing undercooked eggs, and on the next slide, from 1995 to 1998, there were 794 Salmonella Enteritidis outbreaks of infection reported to the CDC. These involved just over 28,600 illnesses, 2,800 hospitalizations, and 79 deaths. Again, greater than 75 percent associated with foods containing undercooked eggs.

On the next slide, please.

This is an important point that I'll move through fairly quickly. We describe this in depth in our hazard

characterization of the risk assessment report. But if we want to get an estimate of what's going on today in terms of the number of illnesses from *S. Enteritidis* in shell eggs, how can we do that?

This is an example. This is data from the year 2000, and what you can see on number one is that the number of *Salmonella* illnesses ascertained by FoodNet was 4,330. The number of isolates that were serotyped was 3,964, and of those that were serotyped, the number that were identified as *Salmonella Enteritidis* was 585.

The ratio of serotyped isolates that were SE is therefore .15, which gives us an estimated number of illnesses from *Salmonella Enteritidis* attributable -- excuse me. I should say -- yes, that's correct. From *Salmonella* attributable to *Salmonella Enteritidis* is 639. The population in the FoodNet catchment area during the year 2000 was 30,500,000. Therefore the incidents of *Salmonella Enteritidis* infection in the catchment area during that time is 2.1 per 100,000 persons.

The U.S. population at that time, you'll see there, 281 billion, which gives us an estimated cases of *Salmonella Enteritidis* in the U.S., based on those data, 5,896. However, we know that there's -- there needs to be an illness unreporting multiplier. Not everyone who develops *Salmonellosis* will go see a doctor. Not everyone who goes to

a doctor will have a stool culture taken, and so forth. And so not every case of Salmonellosis can be ascertained by FoodNet.

And so based on some previously published results, particularly from Paul Mead and updated a little bit later, we can apply an under-reporting multiplier of 37. You have one illness ascertained, 37 actually took place, and that gives us a total number of illnesses from Salmonella Enteritidis in the year 2000 of just over 250,000.

Now, the proportion of those that are due to eggs; in our report we say that it's 80 percent. So that takes the number down to 174,356. Whether or not the 80 percent is an accurate reflection, as I'm clear, is based purely on outbreak data, not on sporadic infections.

There's some indication that the number should be a little bit lower, maybe around 60 or 70 percent. Nevertheless, this gives us a ballpark figure of how many illnesses we think occurred during 2000. Our colleagues at the CDC have spent a long time doing this sort of work, and these are our estimates at FSIS, but ones that CDC come up with are similar.

Okay. So let me end with just a couple of conclusions. On the next slide, please. You'll have to click once. There you go.

Based on surveillance data shell eggs have been

identified as an important vehicle of infection from S. Enteritidis. Greater than 75 percent of these outbreaks have been associated with undercooked eggs. We know of no outbreaks from Salmonella in liquid egg products in the U.S. up until now, and when I say "we," I mean myself and my colleagues at the Food Safety Inspection Service.

So we know that this is still a problem, public health threat, Salmonellosis from S. Enteritidis, notwithstanding the fact that there appears to be a considerable decline, a steady decline since the mid-90s.

And lastly, why do we create a new risk assessment?

As I talked about at the beginning, we have new data that's become available since 1998, improved modeling techniques that we believe allows us to create robust risk assessments for S. Enteritidis in shell egg and Salmonella species in liquid egg products. And the results of risk assessments are what you'll hear after the break.

Thank you.

(Applause.)

MR. LANGE: Thank you, Carl. As Carl mentioned, we'll now take a break of approximately 15 minutes. Thank you.

(Off the record at 10:10 a.m. and back on at 10:28 a.m.)

MR. LANGE: Are we technically ready and back on?

MS. UNIDENTIFIED: Yes.

MR. LANGE: Okay. Thank you.

Okay. Welcome back from the break. I got just a couple notes I want to mention before we get on to our next speaker. FSIS will be posting the three Power Point presentations on the FSIS website. So the technical glitch with Victoria's presentation that wasn't here today, it will be posted on the FSIS website.

I'm going to say now, and I'll mention this again before we get to Q&A's, the -- since this is being reported, when people ask questions here in the audience, I request that people very clearly pronounce their name and affiliation before they ask a question.

And I'll ask our speakers to try to bend this microphone, I guess, a little more forward because some of our people out at websites are having a little trouble hearing the audio.

I was telling a couple of people on the break, I sort of -- I violated that first sort of principal of speaking in public that says, "Know your environment." Well, when you get up here, Vicky could say she was standing, but it's unbelievable how low the place where you can put your notes are, and they sort of warned me this morning, you know, it's webcast. Look into the camera.

You know, and then I was thinking, my notes are down there, and what if I forget them, and I can't hardly --

I mean, I need new glasses terrible. So I was -- you won't believe how much I was struggling up here to figure out whether I was going to, you know, do this or this or whatever. Without -- I'll just mention this to see if we can sort of get more volume into the microphone.

Okay. Let's get started again.

The final presentation today where we actually get into describing a little more of the actual models themselves, and the results that were generated from the models will be presented by Dr. Wayne Schlosser.

Wayne Schlosser is a public health veterinarian in the risk assessment division of the Office of Public Health Science. He has a masters of public health degree, and is a diplomat of the American College of Veterinary Preventive Medicine with a sub-specialty of epidemiology. He has been involved with Salmonella Enteritidis since serving in the SE pilot project in Lancaster, Pennsylvania in the early 1990s. Welcome.

DR. SCHLOSSER: As we go along, check the volume for me. Let me know if I'm too low from the webcast people if they let me know.

As we said before, we'll actually be looking at two different risk assessments today. One is for Salmonella Enteritidis in shell eggs, and the other is for all Salmonella serovars in egg products.

We tend to see only Salmonella Enteritidis in shell eggs, while we see many types of Salmonella in egg products.

So it's easier to consider shell eggs and egg products separately.

For each risk assessment, we'll first review risk management questions. Then we'll give a very brief overview of the model. And finally we'll give the results of the risk characterization. So first we'll review the risk assessment of Salmonella Enteritidis in shell eggs.

The Salmonella Enteritidis in shell eggs risk assessment addresses three different risk management questions. The first one is, "What is the number of illnesses per serving and the annual number of illnesses from Salmonella Enteritidis and pasteurized and non-pasteurized shell eggs?"

Question two is, "What is the effect of temperature and length of time in days before eggs are collected after they are laid by the hen, and then refrigerated and further processed on the estimated risk of illness?"

And question three is, "What is the number of Salmonella Enteritidis in shell eggs before and after a specified pasteurization scenario?"

The Salmonella Enteritidis in shell eggs risk assessment uses a farm-to-table model. This slide shows a graphical overview of the model. An egg starts with a

certain number of bacteria. Those bacteria can grow until, and if the egg is pasteurized.

After pasteurization, if bacteria are still remaining in the egg, they're able to grow again. The egg is then allocated into one or more servings, and the servings are cooked. Finally, the number of bacteria left after cooking are used as an input into the dose response function to determine if illness occurs.

The model considers several things to estimate illness. We model contaminated eggs one at a time from farm to fork. First we must determine if the egg is contaminated, and if the egg is contaminated, how much SE is in that egg? Then we estimate the growth due to storage and the decline due to cooking. Then we estimate how much of the egg was consumed by one or more persons. And finally, we determine whether the consumed doses would cause illness.

Each of these determinations requires collection and analysis of the available information, construction of probability distributions to represent the variability in different practices, and then incorporation of these distributions into a computer model.

The first step in modeling illnesses is determined whether an egg is contaminated. This depends first on whether the flock is infected with SE. Producers routinely test incoming chicks and pullets for SE, but SE can still

enter the house in other ways, and insect and rodent factors can maintain SE in houses that have been cleaned and disinfected.

If the flock is infected, we must determine whether the chicken that layed an egg is infected. Individual hens vary in their exposure and susceptibility to SE. Thus, only a fraction of the hens will actually be infected.

Finally, we must determine whether the infection is actually passed to the egg. Not all infected hens pass SE into the egg, and those that do, usually do so only for a short period of time. Data for this estimate came from FSIS surveys, ARS studies, and from the published literature.

If the egg is infected, we must determine how much SE is in the egg. This depends on the location of the contamination within the egg, whether the contamination is on the shell membrane, in the albumen, in the vitelline membrane, which is the membrane that separates the yolk from the albumen, or within the yolk itself. It also depends on individual egg or hen variability, and we used information from the published literature, and from an analysis of data that was provided to us by researchers.

Once we know that the egg is contaminated, we need to know how much the SE grow while the egg's in storage. We model the time and the temperature of the egg at each step of the farm-to-fork continuum.

Along with ambient temperature, the temperature of the egg depends on whether the egg is stored in the center or the edge of a carton or a case or a pallet. Eggs that are stored in the center of a pallet will naturally take longer to cool than eggs stored at the edge, but if eggs are stored long enough and warm enough, then growth will occur. We used a diverse set of data sources to estimate both how SE grows and the types of conditions to which egg will be exposed in that farm-to-fork continuum.

After SE grow in the egg, they can then be killed by cooking. This depends on the type of serving and then the type of cooking. Eggs may be served as eggs, or they may be served as ingredients in some type of a mixture, such as a cake. Egg may also be incorporated into a beverage, such as eggnog.

The number of bacteria that are killed also depend on how thoroughly the egg is heated. For instance, soft boiled eggs are not as cooked as much as hard boiled eggs, and would be expected to have more surviving SE. We used data from CSFII and from the published literature to estimate the types of servings and expected log reductions for each type of serving and cooking method.

It's important to remember that one egg may serve more than one person. This can occur when eggs are broken out into a bowl and held for later use, or when eggs are

simply combined into a recipe. CSFII tells us how many grams of egg are in a serving, but it doesn't tell us how many eggs went into the serving. So a recipe that serves ten means that one contaminated egg in a recipe will serve ten people.

Each of these ten people would still -- would get one tenth of the dose, but that dose may still be enough to cause illness.

Finally we need to determine whether the amount of SE consumed will cause illness. The dose response function used in the model is taken from the joint FAO/WHO report developed by the joint expert meetings on microbiological risk assessment. The extents of peer review of this report, we think, makes the choice of this dose response model fairly easy to defend.

Let's now do a quick review of the results. As we talk about the results of the model, we'll refer to the baseline model and the baseline results. The baseline model uses our best estimates of input values and distributions, and it's designed to model current practices, reduction, processing, and preparation.

So the first risk management question was, "What is the number of illnesses per serving and the annual number of illnesses from Salmonella Enteritidis in pasteurized and non-pasteurized shell eggs?" We will consider this question in parts. Again, when we think about servings, we often think

of how many eggs or how many grams of product a person eats.

So one individual might eat one, two, or three eggs for breakfast.

But remember, also, that an egg may serve more than one person. So if we make scrambled eggs by cracking 12 eggs into a bowl, scrambling them, cooking them, and then feeding six people, then each of those 12 eggs served six people. So first we determine the number of illnesses that each egg can cause. The estimated illnesses per non-pasteurized shell egg is about seven per million.

There are about 50 billion shell eggs consumed as table eggs annually in the United States. A table egg is one that is available to cook as an egg, or to be incorporated as an ingredient into some type of recipe. So given 50 billion table eggs and about seven illnesses per million, we would expect to have about 350,000 illnesses.

Earlier Carl presented an estimate of about 174,000 human illnesses based on surveillance data from the year 2000. Three hundred fifty thousand is more than that. The estimate from the surveillance data is based on the assumption that there are 37 total cases for each reported case. This multiplier, however, will have some uncertainty associated with it, which is a product of the uncertainty underlying the various parts of the multiplier. So it is to be expected that the estimate of 174,000 will lie within some

range of uncertainty.

So we look to see how close our estimate of 350,000 illnesses was compared with epidemiologic estimates when we consider this uncertainty. We used FoodNet data for Salmonella and for SE to develop a distribution to describe the uncertainty associated with the estimate of SE cases due to shell eggs. As you can see, the baseline model that result, which is that vertical line in the middle, it falls within the uncertainty estimate associated with the epidemiologic estimate.

Recently we've worked with some of our colleagues to narrow this uncertainty, and this yellow line represents our most recent distribution. The new range of uncertainty is much more narrow, and the baseline model estimate now appears near the upper end of this distribution. It's still, however, within the bounds of uncertainty, and thus, should be a useful model of the farm-to-table continuum.

There are about 125 billion servings of table eggs annually. Thus there are about 2.8 illness per million servings of table eggs.

We modeled two pasteurization scenarios. In one, we modeled the 3-log pasteurization. This is equivalent to multiplying the number of bacteria in an egg by .001, or reducing the number by 99.9 percent. This reduction in bacteria due to pasteurization results in an estimate of

illnesses per egg of about two per million. If we model a 5-log pasteurization, we get a reduction to about one illness per million eggs.

The corresponding annual number of illnesses with these pasteurization scenarios is 110,000 for the 3-log pasteurization and 52,000 for the 5-log pasteurization. And these annual number of illnesses correspond with about nine illnesses per ten million servings for the 3-log pasteurization scenario, and about four illnesses per ten million servings for the 5-log pasteurization scenario. So this is a summary of the answer to question one.

Question two was, "What is the effect of the temperature and length of time in days before eggs are collected after they are laid by the hen and then refrigerated and further processed on the estimated risk of illness?"

To answer this, we looked at different scenarios for refrigeration temperature, different scenarios for time until refrigeration, and the different scenarios for pasteurization, for a total of 27 different combinations. Storage at 53 or 60 degree Fahrenheit resulted in almost as many or more illnesses as did the baseline scenario. This is because many producers and processors already refrigerate eggs shortly after laying.

There was, however, a noticeable difference when

eggs were stored at 45 degrees shortly after laying. This chart shows the annual number of illnesses for different pasteurization scenarios for egg stored at 45 degrees within 12, 24, or 36 hours of laying. The orange bars represent the baseline scenarios that we examined earlier. The turquoise bars represent the result of storing eggs at 45 degrees within 36 hours of lay. The red bars show the effect of refrigerating eggs within 24 hours of lay. And the light yellow bars show the effect of refrigerating eggs within 12 hours of lay.

Because most producers collect eggs twice a day, refrigerating eggs within 12 hours of lay is essentially the same as refrigerating them as soon as they're collected.

This is a table showing the results we saw in the previous chart. Note that a combination of rapid refrigeration plus pasteurization is much more effective than either mitigation alone. Without refrigeration SE bacteria in eggs can quickly reach high levels that pasteurization cannot eliminate. Without pasteurization, many more eggs remain contaminated so that later exposures to high temperatures result in rapid growth later on in the continuum.

Question three is, "What is the number of Salmonella Enteritidis in shell eggs before and after specified pasteurization scenario?" Well, in short we saw

that pasteurization decreases the number of bacteria, but regrowth of these bacteria could still occur if there are surviving bacteria after pasteurization.

The number of bacteria at each model stage is actually a distribution. It may be easier to think of these distributions in terms of their ability to cause human illness. Thus, we can think of the potential for human illness at various model stages if humans were to consume raw eggs at those stages. This is, of course, unrealistic, but it does show how the potential risk of eggs changes in that farm-to-table continuum.

This light blue line shows the number of illnesses expected after each stage if we do not have pasteurization. If all eggs were consumed raw in the layer house, there would be about 600,000 illnesses. The potential illnesses increase to about one and a half million by the time we reach the end of home storage. Finally, cooking reduces the potential illnesses to about 350,000, which is our baseline value.

If eggs are subjected to 3-logs of pasteurization, the potential for human illness drops substantially. Furthermore, the potential for additional illness does not increase as rapidly. This is because bacteria have now been eliminated from most contaminated eggs. Cooking further reduces the risk. 5-logs of pasteurization further reduces the potential for eggs to cause human illness.

The SE in shell eggs risk assessment baseline model accounts for variability in the system by iterating through specific values and distributions. The effect of uncertainty was evaluated by running a series of scenarios. Each scenario consisted of setting all inputs except one to the baseline value. The remaining input was set to either an upper or a lower bound.

These bounds were either set arbitrarily or by evaluating the uncertainty of the parameters. This nominal range sensitivity analysis is useful for evaluating the effect that each input has on the model output, whether we were able to characterize the uncertainties probabilistically or not.

Inputs that had the greatest effect on model output through the SE in shell eggs risk assessment were related to storage temperatures, growth parameters, and the prevalence of contaminated eggs. Additionally, as noted earlier, pasteurization greatly influences the estimates of human illness.

In summary, the baseline model estimates about 350,000 illnesses per year. Quick refrigeration at 45 degrees fahrenheit and pasteurization at 5-logs are both effective in reducing illnesses, and the combination of refrigeration and pasteurization is more effective than either alone in reducing illnesses.

Now, we'll review the risk assessment of Salmonella species in egg products. As with the risk assessment for SE in shell eggs, we'll review the risk management questions, and we'll give a brief description of the model. And then we'll discuss how we have done some anchoring of the pasteurization estimates to the FSIS and product sampling, and we'll look at the results of the risk characterization.

The first risk management question is, "What is the number of illnesses per serving, and the annual number of illnesses from Salmonella species in pasteurized egg products; liquid, whole eggs, yolks, and egg whites?"

And the second question is, "What is the number of Salmonella species in a liter of egg product, whole, yolk, and white, before and after a specified pasteurization scenario?"

I'd like to point out some differences between the two risk assessments. The egg products model is for all serovars of Salmonella, while the shell egg model is only for Salmonella Enteritidis. The egg products model is a processor to table model, while the shell egg model is a farm-to-table model.

This is not as big a difference as might appear because the effect of on-farm mitigations could be modeled later on as a decrease in the incoming level of Salmonella in the liquid egg product. Lastly, the focus in the egg

products model is on illnesses per serving, while on the shell egg model it is on illnesses per egg.

The egg products model is built in a similar way to the shell eggs model. Like the shell eggs model, the egg products model is fairly complex, containing many distributions and tended to represent the great variability in use, storage and cooking of egg product servings. And because there are relatively few contaminated servings, the model must run about ten times as long as the shell eggs model to reach the same level of stability.

The egg products model first determines how many Salmonella are in a serving of liquid egg product, and it then models the decline due to pasteurization, growth due to storage, further decline due to cooking, and then whether the dose causes illness. The number of Salmonella in a serving of liquid egg product depends on the initial level in white, whole or yolk, and on how large a serving is consumed. We use the FSIS raw egg product baseline study to determine Salmonella per gram.

Unlike shell eggs, it is assumed that all liquid egg product is pasteurized to some level, but a claim of Salmonella due to pasteurization is dependent on the type of product and whether the product had any ingredients added to it, such as salt or sugar. These added ingredients before pasteurization affect the time and temperature to which the

product can be subjected during pasteurization, and ultimately the level of Salmonella in the product.

Seven combinations of products and additives were specifically modeled. We used a recent study sponsored by the United Egg Producers, which supply data for this input.

As with the shell eggs model, growth of Salmonella during storage is dependent on time and temperature. We modeled growth of the same model as for shell eggs. We did not, however, have time and temperature data available, so we used information from a previously convened expert elicitation panel.

Also similar to the shell eggs model, the decline of Salmonella due to cooking is dependent on the type of serving and whether the product is served as an egg, as a mixture in a recipe, or as a beverage. And then how thoroughly cooked the product is. As with shell eggs, we used data from CSFII, and we used log reductions in shell eggs as a proxy for the log reductions that we would expect in cooked egg products. The same FAO/WHO dose response function is used for the egg products model as for the shell eggs model.

This slide shows the main model stages. Since this is not a farm-to-table model, there is no provision of growth for growth of bacteria before the pasteurization.

Now, the Salmonella in serving before

pasteurization is based on the FSIS egg products baseline study, and the pasteurization factor is based on the UEP sponsored study. This information was used in the development of the model, but there's an additional source of information that was not used in the development of the model, and this is FSIS and product sampling. So we anchored the model to this information for one product type, and that was for egg white.

We anchor a model to observe data to ensure that results are consistent with the real world. We anchored the egg products model, the end product sampling, because we believed that the unanchored model gave a high estimate of human illnesses compared with the epidemiologic data.

So what we did was to adjust the pasteurization levels until we got results consistent with FSIS end product sampling. The only level that needed to be adjusted was the one for egg whites. This level was adjusted from a 3.25-log reduction to a 5-log reduction due to pasteurization. The other egg product types were consistent with FSIS end product sampling, and thus, they were not adjusted.

Now we'll take a look at the results for the egg products model. The first policy question was, "What is the number of illnesses per serving and the annual number of illnesses from Salmonella species in pasteurized egg products, of liquid whole eggs, yolks and egg whites?" As

for shell eggs, we divided this question into parts.

This chart shows the expected illnesses per serving for pasteurization scenarios ranging from 5 to 12-logs of reduction due to pasteurization. At this level of pasteurization, the effect is fairly linear. so increasing pasteurization from 6-logs to 7-logs means reducing the illnesses per serving by nearly a factor of ten. This chart assumes that all egg products would be pasteurized to these given pasteurization levels.

We next look at the annual number of illnesses. This chart shows the annual number of illnesses expected for each of the given pasteurization levels. This chart shows the straight line relationship seen in the previous chart. There would be about 240,000 illnesses given a 5-log reduction, about 28,000 given a 6-log reduction, and about 2,900 given a 7-log reduction.

The baseline model result is about 37,000 illnesses. Now, this doesn't mean that all egg products currently undergo what looks like about a 5 and a half-log reduction. Rather, it means that if we aggregate the illnesses for all of the seven egg product types that we simulated, with the baseline pasteurization, storage, and cooking assumptions, then that adds up to 37,000.

This next slide shows the same information in tabular form. The second question is, "What was the number

of Salmonella species in a liter of egg product, whole, yolk and white, before and after a specified pasteurization scenario?"

This chart shows the number of Salmonella per liter before and after specified pasteurization scenarios. On the X axis are levels of Salmonella per liter. On the Y axis is the percent of liters of egg products that are at or below the corresponding levels of Salmonella. The vertical white line represents one Salmonella per liter.

The levels of Salmonella before pasteurization in whole egg is shown in this line. Because the line intersects the vertical, white line at ten percent, we would expect that ten percent of liters would have less or an expected value of less than one Salmonella, and that 90 percent would have more than one Salmonella per liter. Over 50 percent would have more than 1,000 per liter.

The next line shows the results of a 3-log reduction due to pasteurization. Now, only about half the liters would be expected to have one or more Salmonella. With a 6-log reduction, less than five percent would be expected to have more than one Salmonella, and with a 9-log reduction, it is extremely unlikely that any Salmonella would survive.

This summarizes what we saw on the chart. Nearly all liters of raw, whole egg product before pasteurization

would be expected to have one or more Salmonella bacteria. And pasteurization to 9-logs of reduction virtually eliminates Salmonella.

The model output is sensitive to the incoming level of Salmonella, log reductions due to pasteurization, and how the end product is used, especially how it's cooked. In summary, the anchored baseline model estimates about 37,000 human illnesses. The baseline model assumes that all egg products are pasteurized to effect at least a 5-log reduction. Additional increases in pasteurization result in corresponding decreases in human illness.

That concludes my presentation. Thank you.

(Applause.)

MR. LANGE: Thank you, Wayne. The next phase of our meeting will be the question and answer session, and as I discussed earlier, we will begin with any questions from the audience here in Washington, D.C., and there's microphone in the center of the room. Remind people if they have a question, go to the microphone, state your name clearly for the recorder, and your affiliation.

So with that, we can open the floor for questions from people in the room here, although I had one comment that I get to add first. And this is a -- if you recall Dr. Schroeder's slide showing Salmonellosis going up in the 60-plus population, and then he talked about senior citizens,

and as people of FSIS know that next year, next August, I have one of those milestone birthdays. So I'm recommending mature adults. Okay. We're open for questions in Washington, D.C. here.

MR. WOOD: Am I technologically on line here?

MR. LANGE: We can hear you here?

MR. WOOD: Okay. I'm Richard Wood. I'm Executive Director of Factor of Food Animal Concerns Trust. We have been involved in working on egg safety and Salmonella Enteritidis for a number of years. We were present and involved in the first risk assessment that USDA/FSIS did. We've been working with FDA on the development of the Egg Safety Action Plan, and for about ten years, beginning in 1991, we had a Salmonella Enteritidis model control program working with 14 smaller farms in Pennsylvania.

The questions that I have basically relate -- focus on the shell egg portion of the risk assessment. And particularly reflect on its relationship to the proposed FDA rule. And so first, could someone speak to the relationship of the two; were FDA involved in formulating or establishing some of the risk management questions that the risk assessment was to address?

Am I allowed to ask more than one question, by the way?

DR. MASTERS: Yes. Well, I'm only allowed to

answer one at a time just to make sure that we can get through them all.

DR. WOOD: Right. There's only a few.

MR. DERFLER: The answer is, we have worked closely with FDA, both -- all the way through this process. They did have input in the stuff you see today, and we have been working with them.

DR. WOOD: Right, because for me as a consumer, it's out of sync. I mean, I would've loved to have seen this risk assessment before the risk management FDA options were put forward, and then that could've informed it. But still since the FDA rule is a proposed rule, and this is a proposed draft, I guess it makes sense that they almost came out simultaneously for that perspective. So I welcome that response.

And now some specific questions that may or may not apply as I make the link between the two. Did you consider the impact of cooling and the quick refrigeration that you spoke of in terms of Salmonella rates in -- within the egg and its multiplication; did you look at that at all in terms of its impact on cracks?

One of the issues that egg processors and producers face in the cooling process, you know, is the occurrence of cracks, which may be seen only as an egg quality issue, but in our view it's also an egg safety question.

DR. SCHLOSSER: You mean, did we --

DR. WOOD: Did you factor that in? Did you consider cracks at all --

DR. SCHLOSSER: No.

DR. WOOD: -- in terms of the -- was there a reason for doing that, or is this a stupid question?

DR. SCHLOSSER: No, it's not a stupid question because what we're evaluating, or if we can cool eggs to this temperature within this amount of time, what would be the results? We're not looking at the technology that might not be available to do these things.

DR. WOOD: I see, but in our view or my view and out of our experience, I mean, rapid cooling from a warm egg at some point, from farm through processing, does have an impact on cracks, and that may be something that you would want to consider in terms of SE contamination rates in the overall healthiness of the egg.

MS. LEVINE: If we get to the point of rulemaking, that would be something that we would consider.

DR. WOOD: Okay. All right. Another question that relates again to coming from the rule perspective with FDA and applying it or seeing how this SE risk assessment might apply, is it possible to determine by week the SE rates in the flock? You have, as I read the risk assessment and, of course, it's very long and the playoffs were on the last

couple of nights, and so it was kind of hard to work through it all in detail.

But somewhere during the seventh inning I think I read that the -- that you really had only one overall flock figure for SE contamination rates during the first lay cycle.

Do you have a week-by-week estimation of SE contamination? I know you weren't able to do it seasonally, but that would be helpful in affirming -- in determining when a test -- an environmental test might take place within the life of the flock if there were to be only one environmental test.

DR. SCHLOSSER: No, we didn't do that either because what we were looking at was the total number of contaminated eggs that would be produced by the U.S. flock. I can relate back to some previous experience on that question, and at the pilot project looking at lots of flocks and lots and lots of eggs, we did see a -- what appeared to be a slight increase as the flocks got older in the number of both environmental samples we would see and the number of contaminated eggs we would see.

DR. WOOD: Right. Which is why and based on the data that we had as well from our organization and our SE testing, we set it up 40 to 45 weeks. But I was hoping, perhaps, that this risk assessment might be able to be definitive at that point to help, but I guess we're asking different questions of the risk assessment.

So perhaps -- and this may be coming from that same context, though. After molt, you did indicate in the risk assessment that SE is more likely to occur -- appear closer to molt than later on in the life of a flock after molt. Do you have a week-by-week assessment on that as well, because there -- the proposed rule from FDA sets it at 20 weeks, and that was set, I believe based on the experience of P-CAP and the pilot study, but do you have a week-by-week data of that point?

DR. SCHLOSSER: We have for that only the summary data from the pilot study, --

DR. WOOD: Okay.

DR. SCHLOSSER: -- but which again show that increase and the decreased to where you didn't see a difference after 20.

DR. WOOD: All right. Okay. Was there any -- this is my last question, and I think I must be coming at this risk assessment, which may be informative to you, and it certainly is to me, that the risk assessment may not be that informative in terms of helping risk management in developing risk management interventions on farm.

I'm really not sure how those two, and of course that's an FDA concern, but at the same time, as you're doing a risk assessment, addressing shell eggs, one would think that there could be an application, and that's simply what

I'm trying to make. And so beyond this next question and your response, I would like to know what other applications might be out there that we might look at in terms of applying this risk assessment to the proposed rule at FDA.

But finally, did you determine the success rate of finding SE contaminated eggs in an SE environmental positive flock? And that comes from both UEP -- P-CAPs process and also the proposed rule of when you find an environmental positive, then you test batches of eggs and to see or to confirm whether or not there is SE. Did the risk assessment do any looking at the relationship between a positive environmental sample and positive eggs in that flock?

DR. SCHLOSSER: Well, that type of information is incorporated into how many flocks, or how many eggs we think are contaminated, but we didn't specifically model those type of on-farm mitigations where we would incorporate environmental testing and follow it up by egg testing. We were mostly trying to inform pasteurization and refrigeration scenarios.

DR. WOOD: Are there places then where you think this risk assessment, focusing on shell eggs, has important information to inform the FDA proposed rule on egg safety?

MS. LEVINE: I'm not -- i don't know how FDA might use this. This is intended for our use regarding possible regulatory action perhaps in shell egg packers, but this is

not intended for use on the farm.

MR. DERFLER: I think it's important that you keep in mind the jurisdictional distinction between --

DR. WOOD: Oh, I understand that. Absolutely.

MR. DERFLER: And we're using this to inform our regulatory actions.

DR. WOOD: Which may argue for a single food safety agency. But the first risk assessment, I guess the reason I came at this with hopes of making that link was the first risk assessment in 1998, we were able to make those kinds of links, and I was hoping that this risk assessment in its final form would also enable that kind of information data. So thank you very much.

MR. BALL: Hello. I'm Hershell Ball with Michael Foods. First I would like to compliment the presentations, the quality, and also I know the hours and hours of staff work that went to do this risk analysis. It's interesting read. It does make us have a lot of questions obviously.

I would like to ask a couple of housekeeping questions first. In terms of the availability of all the appendices and supporting material, those -- when will they be available?

DR. SCHROEDER: They will be available no later than next week.

Can you hear me okay?

MR. BALL: No.

DR. SCHLOSSER: How about now? I'll just speak loudly. I don't know what the folks on the -- they will be available, all of the appendices in their entirety, by the middle of next week.

MR. BALL: Okay. And as part of that, the pieces of information that are critical in the presentation of the risk analysis development and hazard analysis, including the FSIS or USDA study on the baseline findings, the numbers, is there be more data available other than abstract?

DR. SCHROEDER: That's a good question. Can I defer to you on that one, Phil, in terms of the availability; can we release it?

MR. DERFLER: I mean, we will make it available as soon as we can.

MR. BALL: Okay. Also critical to understanding the anchoring of the egg products is the data that you're using to anchor that, particularly on the egg white. So if those are available, that would be useful also.

Thank you. I appreciate having those available.

I guess one question in the model that a intervention piece that's in the -- was not discussed here at all in terms of estimating the potential, initial numbers of SE in an egg was vaccination. And I'm particularly interested in that from the point that it is fairly well

understood that that can be a very effective control mechanism, intervention mechanism, and particularly since you had a lot of input from Professor Humphrey in the apparent success of the line mark program UK based on vaccination. Why was that not a -- included in the farm-to-table model?

DR. SCHLOSSER: Again, we didn't model specific on-farm mitigations. There's a variety of things that producers can do to lower the prevalence of SE in addition to the vaccination and things, such as rodent control and cleaning, disinfection, but we model the -- more to inform our pasteurization and our refrigeration interests.

MR. BALL: But it seems like that's biasing your initial estimates of the risk and additional numbers upward in that there should be an appropriate adjustment to that. So therefore your interpretation of the pasteurization in chilling and cooling steps might be different.

MS. LEVINE: Does FDA permit vaccinations?

MR. BALL: To my knowledge, it's practiced in the United States, yes. And our -- my understanding is that it's very effective in reducing the potential for infection, and also for helping to alleviate situations where there might be challenges of SE in the environment.

DR. SCHLOSSER: We'd be interested in any information you have on, say, the percent of flocks that are vaccinated, and then the differences you would expect to see

in contaminated eggs as a result of that.

MR. BALL: Right. I'm not sure I can -- how much of that I could provide, but we'll look inside Michael Foods organization and see what we can.

DR. SCHLOSSER: Sort of what we found, again, in the final project that was vaccination appeared to lower prevalence of contaminated eggs, but it didn't make a difference in the environmental samples. So it's hard for us to make that link without that information.

MR. BALL: But again referring back to the apparent success of the programs in the UK with the vaccination program, given the fact that they do not refrigerate eggs, and they don't really wash their eggs there, and so you have -- but I realize they do, on the line mark program, they have some pretty specific dating relationships, and it's all built around some of Professor Humphrey's studies.

So it seems to me this is a huge oversight in increasing the apparent risk level by because of the apparent high numbers. I think there's probably -- should be a good adjustment factor there.

DR. MASTERS: Again, this is Barb Masters, and I would just comment, not just for yourself, but others listening on the webcast. If someone has data on the percent of flocks in the United States that are vaccinated, and any data that would be useful to our agency, that would be very

-- that would -- data that we'd be willing to look at, but again we would need specific data that would be useful that could inform the risk assessment, and we would need significant data for us to be able to use that kind of information.

So we appreciate the comment, but we would need it in the form of data rather than just as a comment, we would like data to support those kind of comments, and we would welcome that data.

MR. BALL: I'm surprised there's not more data available in a way.

Back to what data is available, though, on page 148, particularly the discussion on the yolk membrane breakdown. I was curious how the data that's used in implications of pasteurized shell eggs and that the -- there's some implications there that there's data that describes the yolk membrane breakdown of pasteurized shell eggs, and I'm not aware that that's out or available.

DR. SCHLOSSER: What we did with that was we extrapolated -- given these higher temperatures that you would have with pasteurization, we did an extrapolation that suggested that we would get complete breakdown and --

MR. BALL: But to what basis and fact would allow you to make that extrapolation?

I think if you look at what's been published, that

you'll see that, in fact, that there is a prevention of the breakdown of the thick egg white, the internal structure and quality indicator of egg white, and if you look at the summation of the literature, around what goes on with the vitelline membrane, it can classically be linked to changes or associated with changes in the internal structure of thick egg white.

As the internal structure of a thick egg white deteriorates, it's thought that there are some similar processes that may be going on with the vitelline membrane itself. Therefore the in-shell pasteurization process does stabilize and prevent the expected deterioration in quality of the internal -- the thick egg white. I believe that there is also reason to suspect, as much reason as you have to suspect there's a decline in the study, that that vitelline membrane is not subject to what goes on in non-pasteurized egg.

There would be several other things I'd like to -- we'll probably want to address in our written comments, but having the anchoring data and the other baseline data would be very helpful. And again, I want to compliment you on the volume and the quality of work and the quality of the presentations.

Thank you very much.

MR. LANGE: This is Loren Lange. I'll just add a

clarification and summarize what will be available for people that are on the website. When there is discussion of anchoring data, FSIS does routine monitoring sampling of egg products, and to the best of my recollection, I think we've been collecting around 2,000 samples a year from egg products as part of our, you know, different micro-projects run out of OPHS.

The second thing that was available, as Dr. Schroeder said, we would get all the appendices up on the FSIS website by the middle of next week, and Phil Derfler mentioned we would get the baseline study that we conducted over the last recent years up on the website as soon as possible.

MS. SHALLO-TESMAR: I'm Hilary Shallo-Tesmar, Director of Food Safety Programs for the Egg Nutrition Center. I have a couple of questions for you.

First of all, it's very clear from the data presented this morning and in the risk assessment that you have illness estimates for Salmonella due to egg products. While you mentioned both today and in the risk assessment that there are no reported outbreaks from the CDC, and egg products have been under mandatory pasteurization by the Egg Products Inspection Act for 34 years, how do you explain the difference between the illness estimates and zero outbreaks in that period of time?

DR. SCHROEDER: Our illness estimate that we presented was probably erroneously high for the liquid egg products. I agree with you. We've never seen an outbreak due to egg products, and so therefore, when we present an estimate that says 37,000, whatever that number is, of annual illnesses, it doesn't make sense.

I think the question we have in my mind is --by that same token, you can argue quite well that our estimate of 350 for shell eggs -- 350,000 is also high, and it probably is. The question is, is the risk assessment, the mitigations that we've shown, are those realistic; can you comfortably use those? You know, we say if you pasteurize to X level, you're going to reduce by Y percent.

Can you use that? If you'll allow me, important distinction is a risk assessment, it's not meant to make estimates of past years or surveillance data. If the question we were trying to answer was, "How many illnesses occurred in the year 2000 from" -- you know, we don't need to do a risk assessment. We need to go to the folks at CDC who do this quite well and say, "What does your surveillance data tell us?"

Where risk assessment becomes very valuable is it can be used as a predictive tool, which surveillance data cannot. So we can say, "Okay. Right now the situation is this. If you introduce a certain mitigation, what can we

expect to see in the future?"

And so to summarize and go back to the beginning, the estimate of illnesses that we have for liquid egg products in my mind is too high. The question is, "Is it reasonable enough that when we show you and say, 'This mitigation will cause this decrease in illness,' can you use that information?"

MS. SHALLO-TESMAR: One other thought on that topic is, I assume that you used the minimum pasteurization requirements in your modeling. The industry puts in an additional factor of protection in that. Would be more accurate to rerun that model with what the industry actually does, and would some industry data on those kind of fudge factors be helpful in the risk assessment model?

DR. SCHROEDER: Yes, industry data, of course, would be helpful for us, and you've hit on the very purpose, I think, of this public meeting is, you know, we're saying, "Here's the best that we can do with the data we have. What can you do to help us? Do you have additional data out there, the industry fudge factor, as you say." You know, if we can get that, by all means, let's rerun the model, and let's work together to make sure we get the best model created.

MS. SHALLO-TESMAR: Okay. One additional question or point of clarification. I want to give credit where

credit is due. The pasteurization kinetic study was funded by the American Egg Board. It was referred to as the United Egg Board. There's also a United Egg Producers, but the American Egg Board is the one that funded that study.

DR. SCHROEDER: Thank you.

MS. WILLIAMSON: CiCi Williamson. I'm with the FSIS food -- Meat and Poultry Hotline. I kind of wanted to make a comment, and I'll also ask a question.

I know this is a regulatory meeting, but there's a great deal of confusion with consumers out there with regard to these products and who's inspecting them. For example, we get a lot of questions to the hotline. One of them said that they'd seen Martha Stewart on a cooking show, and she said that if you had your own flock of hens, that you didn't have to worry about Salmonella. It was only the hens that were, you know, factory raised, so to speak.

The other thing they're confused about is the egg substitutes, which are inspected by FDA and not by our agency, and I guess one question I have is, would they be included in this risk assessment for the pasteurized egg products?

And then the other thing I wanted to mention was that it seems like the -- there are fewer in-shell pasteurized eggs available at the retail level for consumers.

So although this is a great risk assessment, I don't feel

the consumers have access to buying the product.

DR. SCHROEDER: I can answer two of those parts, and then -- I guess the first part is, first lesson, don't take food safety advice from Martha Stewart.

(Laughter.)

MS. LEVINE: Just tell hotline people, "Martha's in jail."

DR. SCHROEDER: The second point, however, is you're correct. I don't know the exact number, but I believe it's less than one half of one percent of all shell eggs produced in the U.S. are in-shell pasteurized. So you raise a good point about the availability to consumers.

I'll defer on the issue of the egg substitute.

DR. SCHLOSSER: By egg substitutes, are you referring to things like Egg Beaters?

MS. WILLIAMSON: Yes.

DR. SCHLOSSER: Yeah, which are constructed with egg whites, and that type of thing's included in the risk assessment. Okay. Yes.

MS. DEWAAL: Good morning. Caroline Smith DeWaal with the Center for Science in the Public Interest.

I do want to thank you for holding this meeting, and actually, it is starting to clarify some of the issues. I shared concerns that Dr. Wood mentioned earlier about the relationship with the FDA estimates and the FDA rulemaking, a

risk assessment is, of course, a snapshot in time, and if you're taking that snapshot before you've got the risk mitigation measures on the farm, which FDA has now proposed, the snapshot a year or two from now or several years once those mitigation strategies are introduced may be very different.

FDA also has a very different estimate of illnesses contained in its proposed rule. I've got in my hand the CDC justification for that 118,000 illnesses, but now that I've seen your baseline data and some of the assumptions, I'm beginning to see that if the baseline data's based on all eggs being consumed raw or in an unpasteurized state, and you start making modifications for percentages that are consumed pasteurized, and then there's also a difference in the percent that CDC used on -- of -- the estimate of SE illnesses linked to egg products from what you've suggested at 80 percent.

DR. SCHROEDER: Yes, may I jump in?

MS. DEWAAL: Yeah.

DR. SCHROEDER: That's a very good point. The FDA in their proposed rule does cite this 118,000 value, which was -- they worked in collaboration with CDC to get, and it's very believable to me. Probably more so than our 350. Again, the question is, "What can we do with that 350?"

The point you bring up about the different estimate

for the percent that are SE, I believe; the issue there is, what I showed you, what we did in our hazard characterization, we call that 80 percent. The CDC has subsequently learned, especially with this recent Clinical Infectious Diseases supplement paper by Kimura, et al, that sporadic infection, eggs might not be as important as they are in outbreak infections.

And so -- although don't quote me. I'm fairly certain in that methodology, they use an upper and lower bounds. They say for the percent of 80 and 60, or thereabouts.

MS. DEWAAL: It's -- the low estimate was 53 percent, --

DR. SCHROEDER: Yeah.

MS. DEWAAL: -- and the high estimate was 79, and they use 66, which was the mid-range.

DR. SCHROEDER: Yeah, and so that's entirely reasonable to do, and there's -- we can do that also.

MS. DEWAAL: Well, and I share the confusion of the previous speaker. FDA says the illnesses are 118,000, but USDA says they're 325,000. That does become a very confusing message for the public, and in fact, reporters who were trying to look at this at the time the FDA proposal came out had trouble characterizing the risk.

DR. SCHROEDER: Yeah. Well, I'll say it. As we

were modeling this, if we had come up with an answer of, say, a million illnesses, then at that point we would've gone back and anchored it at that point probably to the same numbers that the FDA had.

When we got an answer that said 350, we said, "Ah, pretty close," because it was within the range of uncertainty that we had. So that's why that part of the model was not anchored to those numbers.

MS. DEWAAL: And I know there's a benefit to not using ranges, but sometimes in doing this, it is helpful to use ranges, or we think they're between 103 -- you know, 400,000 illnesses. Might make more sense than trying to nail it to 118,000 illnesses. So again, I don't know if you're right or they're right, but I'm beginning to understand the difference between the illness.

DR. SCHROEDER: The other point that's important not to overlook here is that we do have these different estimates, but recognize they were arrived at in entirely different ways. That's just important. It wasn't like we looked at the same data as FDA, and CDC and came up with these two different estimates. That's a very important point.

MS. DEWAAL: And it would be very good for the agencies to cross-anchor.

DR. SCHROEDER: And we are -- we've had several

meetings with the FDA. We realize this is an issue, and that's something that we're trying to work together to accomplish.

MS. DEWAAL: Well, now I want to get to my question because that actually wasn't my question.

My question is, you -- Dr. Schroeder said that the 1998 risk assessment was not sufficient to allow FSIS to develop performance standards in eggs. And so I have one question and one idea.

My question is to Dr. Schlosser. What is the proper performance standard suggested by the risk assessment?

DR. SCHLOSSER: Well, that won't be a question that I'll answer. I'll defer to the risk managers on that one.

MR. DERFLER: And we're not ready to answer that question.

MS. DEWAAL: But you said that --

MS. LEVINE: Egg products --

MS. DEWAAL: -- you were supposed to be -- I mean, that that's the point here. So what's -- what did you come up with? What are the performance standards?

MS. LEVINE: We haven't developed them yet.

MR. DERFLER: Yeah. The point is -- I mean, the purpose of this meeting is to introduce people to a risk assessment. Give people a chance to understand that, ask questions.

We're then going to have a comment period, which -- until November 17th, and then we'll have -- after we get the comments, we'll look at the risk assessment, reassess it -- this is my talk at the end, but anyway, reassess it. And then decide whether we're going to go forward and how we're going to go forward and what we're going to do. So we're trying to have an iterative process, and we haven't made the kind of decision that you're suggesting.

MS. DEWAAL: Well, one thing I might suggest, Phil, and I'm -- you know, I read the executive summary of the risk assessment, and the very concise conclusion saying that pasteurization and rapid cooling are effective mechanisms for controlling SE, and I'm really glad that you came up with this lengthy risk assessment, which essentially confirms common sense. But if we know that, and now you have a lengthy document that seems to tell us that, and you could perfect it.

But if we know that, why don't you put in steps right away that would implement those common sense solutions that are now supported by a risk assessment? Let's not wait until the risk assessment is perfect. If there are risk management steps you could take now, I would urge to take them.

In addition, the issue of monitoring the contamination of the batch in processed egg products, I mean,

your data is very strong that the higher the batch of contamination, the less effective pasteurization is. And we might suggest that monitoring of the contamination of each batch of egg products to determine the level of pasteurization needed might be an effective risk management strategy.

I know you're not at that stage yet, but I -- my big message to you is, don't wait until this risk assessment is perfect. Take -- go ahead with risk management strategies because this is really supporting common sense.

Thank you.

DR. SCHLOSSER: Thank you.

MR. LANGE: It sounds like my comments -- when I was trying to lay the ground work, I think, in my overview is that in the business of modeling and developing these risk assessments, we really did view the numbers that FDA had and our numbers, at least in the same order of magnitude. And we really weren't concerned, but had they been, you know, like Dr. Schroeder said, a million or something, we would've been far more concerned.

MS. UNIDENTIFIED: Try your hand at your computer?

MR. LANGE: Okay. I know we have at least one comment, and I'm going to see if it changed here, that has come across. Okay. I'll bring this over here.

I'm now playing with something we haven't done, and

I can go back up here. And I think this first comment we have actually comes from the FSIS -- the people watching in the FSIS district office in Madison, Wisconsin, and their question, first one at least, was, "Did any of the risk assessment or other studies, such as UEPs include restricted eggs?"

DR. SCHLOSSER: You mean restricted eggs specifically or --

MR. LANGE: Well, I'm not --

DR. SCHLOSSER: I guess I don't understand the --

MR. LANGE: Yeah, I'm not sure I understand the question because if they're restricted, they shouldn't be in these products. So, I --

DR. SCHLOSSER: They would go into the breaker, and as such, we would -- you know, they would go into the model, but we're not looking at specific types of eggs at the pasteurized --

MR. LANGE: That's right. Okay.

And now I will be able to go on down and see if we did get another question from --

MR. UNIDENTIFIED: I think you're just moving the camera.

MR. LANGE: Someone said this is fun.

(Laughter.)

DR. SCHLOSSER: It's fun for us.

MR. LANGE: From what I can tell there isn't any other questions that have come in over our experiment with using this system for a public meeting, but if anyone is out at one of those sites and didn't get their question, make sure that, you know, that we get the question somehow at FSIS so that when the public record is available, that questions that anyone had at a website do get into that record. We will make sure that that occurs, and we have one final form that people could've called in, and I guess -- has anyone called in?

(Pause.)

MR. LANGE: I guess not. So at this point that ends our question and answering session, and we move to the final agenda item, which Phil Derfler, who is our Assistant Administrator of the Office of Policy, will provide closing remarks.

Thank you.

MR. DERFLER: And these won't take long.

First of all, I wanted to thank the people from the Strategic Initiatives Partnership and Outreach staff who played a really essential role in putting on this meeting, and their contribution was made more difficult by the need to have this webcast. So to Sheila Johnson, Kathleen Barrett and Mary Gioglio, we want to say thank you very much for your contribution.

I want to thank the people on the panel for their -- for appearing and their presentations. I think they were obviously very valuable, and as your comments reinforced. I also want to thank you for your questions.

Now, just for next steps, today -- as I briefly touched on before, today we tried to give you an introduction to the risk assessment. We tried to answer your questions that were raised by the presentation. On October 18th, as Mr. Lange said, we placed the risk assessment on our website. We're providing 30 days for comment. That means by November 17th, we would like to receive any comments that you have.

Now, why is it important that you comment? First of all, we would like to make the risk assessment as good as possible because it is important. It doesn't have to be excellent, but it needs to be at least good, and as good as we can make it.

Second, the risk assessment needs to be as good as it can be because we intend to use it in various ways as we go through and make our risk management decisions.

As Ms. Levine discussed, we're contemplating proposing performance standards for *Salmonella Enteritidis* in shell eggs, and for *Salmonella* species in egg products, or if not, performance standards some other, perhaps, alternate regulatory approach.

It will help us answer a number of questions -- the

risk assessment will help us answer a number of questions that we need to consider as we go through in making our risk management questions. For example, are there problems with shell eggs and egg products that require that we go forward with rulemaking? I think this is a fundamental question. And the risk assessment, while it won't be determinative, will be an important factor that we'll consider.

If the answer to either question is yes, that it does make sense for us to go forward, we would then use the results of the risk assessment to help us structure the performance standards, or to help us determine what the risk management approach should be. Again, it will not determine it, but it will be an important factor in our thinking as we do that.

And finally we'll use the risk assessment to assess the benefits of mitigation strategy, and use those and weigh them against the costs of what the strategy will be. Those are all things that we need to consider as we go forward.

Now, I would say we're not interested in this time as to whether or not we should go forward with performance standards or something else. What we're interested in is comments on the risk assessment itself.

Now, we will respond to the comments that we get on the risk assessment, either as part of any proposed rule or if that's not the direction we go, we will respond to them in

making the risk assessments public in some other way.

So with that, again I want to thank you for your attendance, for your attention, and for your questions. And we encourage you to submit your comments.

Thank you very much.

(Whereupon, the proceedings were concluded at 11:55 a.m., this date.)

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CERTIFICATE

In Re: USDA/FSIS Strategic Initiatives, Partnerships & Outreach Staff

Place: Washington, D.C.

Date Held: October 22, 2004

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